

JUN 27 2003

**Summary of Safety Information**

**Premarket Notification, Section 510(k), K023378**

**EUROSURGICAL, S.A.**

**JUNE 20, 2003**

**Regulatory Authority:** Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:** ***ORIA CLARIS***  
**Common Name(s):** Posterior spine system

2. **Classification Name(s):**  
Pedicule Screw Spinal System  
Spondylolisthesis Spinal Fixation Device System

3. **Establishment Information:**  
**Name:** Eurosurgical, S.A.

**Number:** 9032545

**Address:** BP 23-18, rue Robespierre  
Beaurains, FRANCE 62217  
33 3 21 21 59 60 – voice  
33 3 21 21 59 70 – fax  
www.eurosurgical.com

**Classification(s):**

**§ 888.3070 – Pedicle Screw Spinal System; Spondylolisthesis Spinal Fixation Device System**

**Device Class:** Class II for the requested indications

**Classification Panel:** Orthopaedic and Rehabilitation Devices Panel

**Product Code(s):** MNH and MNI respectively

5. **Equivalent Predicate Device:**

Eurosurgical, S.A. believes that the ***ORIA CLARIS*** is substantially equivalent to the following legally marketed spinal device systems:

**MNH - MNI** – Eurosurgical, S.A., K021679

The comparison device uses various rods, screws, crosslinks and other components intended for use in the treatment of spinal instability or deformity. Equivalency can be seen with respect to the design, material composition, company of manufacture and intended use.

6. **Device Description:**

**General system description.** The ***ORIA CLARIS*** includes implantable components that fit together to form a construct for use during spinal fusion surgery. The system contains components of various designs and sizes that allow the surgeon to build an implant system to fit the patient's individual anatomical and physiological requirements. Selection of the necessary components is addressed in the surgical protocol.

**Indications for Use:**

**MNH - When used as a posterior pedicle system, the device is indicated for use in skeletally mature patients L3 & below who are:**

- having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint;
- receiving fusions using autogenous bone graft only;
- having the device fixed or attached to the lumbar and sacral spine; and
- having the device removed after the development of a solid fusion mass.

**MNI - Posterior pedicle systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T-10 – S1/2):**

- degenerative spondylolisthesis with objective evidence of neurologic impairment
- fracture
- dislocation
- scoliosis
- kyphosis
- spinal tumor
- failed previous fusion (pseudarthrosis)

**Materials.** The titanium components are made of surgical implant grade CP Titanium and titanium alloy (6al4Vti). The titanium materials comply with ASTM F 67, Gr. 2 and ASTM F 136 and ISO 5832-2 and ISO 5832-3 respectively.

**The basic system components include:**

Connectors – links the rod to the screw

Nuts & Locking Screws – Fastens screw to connector and/or fasten rod to connector.

Rods – Longitudinal members used to join one vertebral motion segment to another.

Crosslinks – Used to join one rod to a parallel rod.

Pedicle Screws – Used to fasten the system to each motion segment.

Sacral Screws – Used to fasten the system to the sacrum.

Unique Instrumentation – Used to manipulate the various components.

The system consists of a series of alloy compatible parts from which various spinal assemblies or constructs may be fashioned. Specially designed connectors, interconnection mechanisms incorporating nuts, screws; longitudinal members (rods) and/or transverse connectors, sacral screws and pedicle screws are offered. The levels of attachment (depending on specific indication) are lumbar and thoracic spine, and the sacrum and may only be used posteriorly. An abbreviated list of anatomical attachment points is listed below.

For the Connectors: T10– S1/2

For the Nuts & Locking Screw: T10– S1/2

For the Rods: T10– S1/2

For the Crosslinks: T10– S1/2

For the Pedicle Screws: T10– S1/2

For the Sacral Screws: S1/2

For the Unique Instrumentation: T10– S1/2

Components of the system should be inserted only with instrumentation specifically designed for this purpose. Briefly, the instruments are used in support of the implantation of the appropriate implant at the corresponding anatomical location. Such use is between T10 and S1/2 inclusive.

7. **Company Contact:**

Mr. Emmanuel Margerit  
**Eurosurgical, S.A.**  
 BP 23-18, rue Robespierre  
 Beaurains, FRANCE 62217  
 33 3 21 21 59 60 – voice  
 33 3 21 21 59 70 – fax  
 www.eurosurgical.com

8. **Submission Correspondent:**

Mr. David W. Schlerf  
 Buckman Company, Inc.  
 200 Gregory Lane, Suite C-100  
 Pleasant Hill, CA 94523-3389  
 925.356.2640 - 925.356.2654 - fax

9. **Performance Standards:**

United States Food and Drug Administration mandated performance standards for this device do not exist. Various voluntary performance standards are utilized. Voluntary standards utilized include ASTM, Standard Operating Procedures, vendor & process certification and qualification procedures, Quality Systems Regulations, ISO materials standards and ISO 9001 series quality regulations.

**Eurosurgical, S.A.** also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

10. **Special Controls:**

Special controls were published in the Federal Register, Vol. 63, No. 143, July 27, 1998 (Orthopedic Devices: Classification and Reclassification of Pedicle Screw Spinal Systems). The following special controls apply to the marketing of this device when used as a posterior pedicle system:

- (i) Compliance with material standards,
- (ii) Compliance with mechanical testing standard,
- (iii) Compliance with biocompatibility standard, and
- (iv) Compliance with specified labeling requirements.

11. **Sterilization Information:**

The **ORIA CLARIS implants** and instruments are not provided sterile. All packaging and labeling must be removed before the next steps. The cleaning and decontamination must be completed before sterilization. The protocol for decontamination and cleaning is:

**Decontamination.** Immerse the implants in a bactericidal and fungicidal solution (i.e., diactyl ammonium chloride) combined with protolytic enzymes, diluted at 0.5% (5gm for 1 liter of water) soak for 30 minutes, rinse out.

**Cleaning.** Automated cleaning in a machine (such as a MIELE machine or sonicator) may be performed. Use only manufacturer recommended cleaning agents. If manual cleaning is used, scrub with a brush using a cleared enzymatic detergent, rinse well under hot tap water and dry.

**Sterilization.** The **ORIA CLARIS** components and instruments are provided non-sterile and must be sterilized prior to use. The devices are clean and have been processed to remove debris and manufacturing residue. Remove all labels and packaging materials before decontamination, cleaning and sterilization. Wash the devices thoroughly with hot water using a typical hospital grade surgical instrument detergent or soap. Ultrasonic cleaners may be employed. All steps leading to sterilization must be performed in accordance with usual hospital practice before first or any subsequent use.

**Sterilization Cycle Validation.** The recommended sterilization process for the *ORIA CLARIS* is steam autoclave sterilization. The recommended sterilization cycle is: saturated steam at 270° F (134° C) for 18 minutes. This is a typical or usual steam sterilization cycle used for surgical implants and instruments. Use of this cycle will produce a Sterility Assurance Level (SAL) of at least  $10^{-6}$ . Validation of the recommended sterilization cycle is achieved via the overkill method, the Kilmer method or a modified AAMI ST32 method 3, protocol B as selected by the biological testing laboratory. Test results are on file at Eurosurgeal, S.A.

Method:	Steam
Preheat Cycle:	25 min @ 110 C°
Vacuum:	5 min @ .8 bar under atmospheric
Heat:	5 min @ 120° C @ 1 bar
Vacuum:	5 min @ .8 bar under atmospheric
Temperature:	270°F (134° C) @ 2 bar
Exposure Time:	18 minutes
Dry cycle:	20 minutes



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 27 2003

Eurosurgical, S.A.  
c/o Mr. David W. Schlerf  
Buckman Company, Inc.  
200 Gregory Lane, Suite C – 100  
Pleasant Hill, California 94523-3389

Re: K023378  
Trade Name: ORIA CLARIS  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: II  
Product Code: MNH, MNI  
Dated: May 16, 2003  
Received: May 30, 2003

Dear Mr. Schlerf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

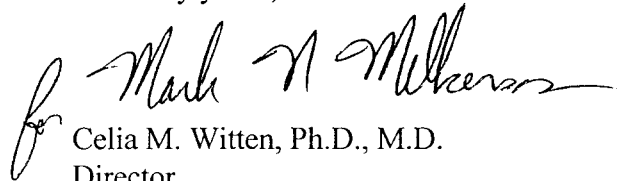
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number : **K023378**

Device Name(s): **ORIA CLARIS**

**Intended Use Statement(s):**

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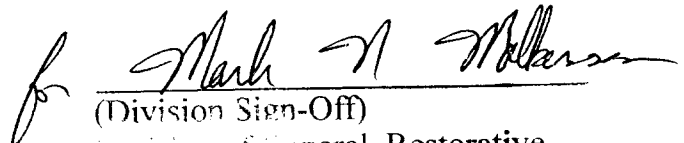
- having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint;
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- fracture
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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

510(k) Number K023378

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional format 1-2-96)